REMARKS

Claims 1-5, 8, 9, 11-15, 17-32, 44-55, 57-62, 64, 65, 67-78 are presently pending in the case. Claims 1, 9, 17, 18, 29-32, 44, 49, 51, 52, 54, 57-59, 62, 64, 65, 67, 70 and 71 have been amended. Claims 16, 56 and 66 are cancelled hereby. Claims 72-78 have been added. The amendments and new claims are supported by the specification and claims as originally filed.

Reconsideration of the present case in view of the above amendments and the remarks herein is requested.

Double Patenting Rejection

The Examiner provisionally rejected claims 1-3, 8-22, 27-32, 44-52, 59-62, and 64-71 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims in copending application 09/568,818. When either the present case or the 09/568,818 case is indicated as being allowable, the double patenting issue will be addressed in the other case.

Claim rejections under 35 USC 103(a)

The Examiner rejected claims 1-5, 8-32, 44-62, and 64-71 under 35 USC 103(a) as being unpatentable over U.S. Patent 6,309,623 to Weers et al (hereinafter Weers et al) in view of UK Patent Application GB 2,065,659 to Materne et al (hereinafter Materne et al). The rejection is traversed.

Weers et al does not render claim 1, for example, unpatentable. Claim 1 is to a particulate composition comprising, inter alia, particles comprising an active agent, a saturated phospholipid and a polyvalent cation, wherein the molar ratio of polyvalent cation to phospholipid is at least 0.05 and is sufficiently high to increase the gel-to-liquid crystal transition temperature of the particles compared to particles without the polyvalent cation. Weers et al does not teach or suggest particles comprising an active agent, a saturated- phospholipid and a polyvalent cation, wherein the molar ratio of polyvalent cation to phospholipid is at least 0.05 and is sufficiently high to increase the gel-to-liquid crystal transition temperature of the particles

compared to particles without the polyvalent cation. Therefore, Weers et al does not render claim 1 unpatentabl .

Additionally, Weers et al and Materne et al do not render claim 1 unpatentable. Weers et al does not disclose a particle have a molar ratio of polyvalent cation to saturated phospholipid sufficient to increase the gel to liquid transition temperature, as discussed above. Materne et al does not teach adding a polyvalent cation to a saturated phospholipid. Instead, Materne et al teaches adding a polyvalent cation to an unsaturated phospholipid (see paragraphs 5 and 6 of the previously submitted Weers declaration of November 25, 2002). Therefore, neither reference teaches the combination of polyvalent cation and saturated phospholipid in the claimed molar ratio.

Furthermore, one of ordinary skill in the art would have not been motivated to combine the teachings of Materne et al with the particles of Weers et al, absent a suggestion to do so. Even if so motivated, the person of ordinary skill in the art would have incorporated the teaching of using a polyvalent cation and an unsaturated phospholipid rather than arriving at the Applicant's claimed invention. Quite unexpectedly, it has been discovered that the gel-to-liquid transition temperature is increased when proper amounts of polyvalent cation is added to a saturated phospholipid, but the transition temperature is not increased when the polyvalent cation is added to an unsaturated phospholipid (see paragraph 7 of the Weers declaration). Thus, the unexpected result of increasing the gel-to-liquid transition temperature and thereby increasing the storage stability of the particles would not have been recognized by the person of ordinary skill in the art without the benefit of Applicant's disclosure. Data supporting this result is described throughout the specification and the Weers declaration.

Since neither reference teaches the claimed combination of polyvalent cation and saturated phospholipid and since it would not have been obvious to modify Weers et al as proposed by the Examiner, Applicant requests withdrawal of the rejection of claim 1. Claims 2-5, 8, 9, 11-15, 17-30, 53, 54 and 72 depend from claim 1 and are also not rendered unpatentable by Weers et al and Materne et al.

Independent claims 31, 32, 44, and 59, all of which recite the molar ratio of polyvalent cation to saturated phospholipid of at least 0.05 are also not rendered unpatentable by Weers et al and Materne et al. Claims 45-52, 55, 57, 58, 60-62, 64, 65, 67-71, and 73-78 depend from one of 31, 32, 44, and 59 and are also allowable over Weers et al and Materne et al.

Claim Amendments

Claims 1, 9, 17, 18, 29-32, 44, 49, 51, 52, 54, 57-59, 62, 64, 65, 67, 70 and 71 have been amended. Except as otherwise discussed above, all of these amendments have been made to remove unnecessary limitations and have not been made for reasons related to patentability.

New Claims

Claims 72-78 have been added to define other aspects of Applicant's invention.

Conclusion

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

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